KYMOS

Bioequivalence Studies

- Clinical trials conducted in European centers
- FDA and EMA inspected, and GCP and GLP compliance
- One-stop shop service including batch release

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BIOEQUIVALENCE STUDIES

KYMOS provides comprehensive bioequivalence studies in a reputed European clinical center and bioanalytical laboratory following EMA and FDA guidelines. High-quality standards as well as narrow timelines and competitive prices are our key elements to deliver successful clinical trials.

CLINICAL STUDY MANAGEMENT

KYMOS covers all the activities directly and indirectly related with the clinical study working side by side with the Phase I Clinical Center:

- Protocol writing
- Submission to Ethics Committee and Regulatory Authorities
- Insurance contracting
- Coordination of test and reference product supply
- Clinical center management
- Clinical center and study monitoring
- Study execution
- Plasma sample shipment and storage

BIOANALYSIS

KYMOS bioanalytical facilities are GLP and GCP compliant, FDA and EMA inspected. KYMOS has a long list of validated methods and offers free of charge set-up and validation for others, fulfilling client's requirements regarding low limits of quantitation and dynamic range. KYMOS counts with a wide experience in highly challenging projects (low stability compounds, therapeutic peptides and small proteins, extremely low limits of quantification, complex methods involving derivatization to increase sensitivity), and important bioanalytical capabilities in terms of number of instruments and variety of analytical techniques available:

- State-of-art LC-MS/MS and HRMS for small molecules
- ICP-MS for metal/organometallic analysis
- ELISA, ECL and RIA for peptide and small proteins

STUDY REPORTING

- Pharmacokinetic data analysis and calculations (Phoenix WinNonlin® software)
- Pharmacokinetic report
- Final clinical report
- Specific reports to answering Authorities requests

SUPPORT ACTIVITIES

KYMOS has GMP certification and Importer authorization for drug products and IMPDs that allows us to offer a package of supporting services:

- IMPD writing or review
- Analytical testing, when additional stability studies are required
- Comparative dissolution profiles between test and reference products
- Importation of reference and test drug products
- Batch testing and batch release